DOCKET NO.: D0188.70132US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dennis Cherok
Serial No:	10/040,936
Confirmation No:	3785
Filed:	January 7, 2002
For:	IMPLANTABLE PROSTHESIS
Examiner:	Julian W. Woo
Art Unit:	3731

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 26 day of May, 2004.

Christine A. Gardner

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMENT ON STATEMENT OF REASONS FOR ALLOWANCE

Sir:

In the Notice of Allowance and Issue Fee Due mailed May 14, 2004 in connection with the above-identified application, the Examiner provided Reasons for Allowance of the claims. In particular, the Examiner stated that:

> [n]one of the prior art of record, alone or in combination, an implantable prosthesis for a tissue or muscle defect having, inter alia, at least one layer of mesh or a material with at least a portion of which permits formation of adhesions with tissue or muscle, a peripheral edge, and a pocket formed in the layer; a first reinforcing member coupled to the layer and supporting an outer area of the layer, and a second reinforcing member coupled to the layer and inwardly spaced from the first reinforcing member. The prior art of record also does not disclose, inter alia, that the implantable prosthesis has a first pocket formed in an inner area of the layer and a separate, second pocket formed in an outer area of the layer. The prior art of record does not that the implantable prosthesis has a barrier layer attached to at least a second layer of mesh material attached to a first layer of mesh material, at least

one pocket defined by the attachment of the first and second layers of material, and a reinforcing member coupled to one of the layers and arranged to reinforce at least an outer area of the layer. None of the prior art of record, alone or in combination, discloses an implantable prosthesis for attachment to tissue or muscle, where the prosthesis has, inter alia, first and second layers of material permitting formation of adhesions, at least one pocket formed between the first and second layers, a layer of barrier material of ePTFE that is resistant to the formation of adhesion with tissue or muscle and covers an entire surface of the second layer, a peripheral edge, and an outer area disposed inwardly of the peripheral edge, where first reinforcing member substantially surrounds and reinforces the outer area, and where a separate, second pocket is formed in the outer area.

Applicants wish to clarify that not all of the claims are limited in the manner suggested by the Examiner. Rather, independent claims 11, 15, 16, 21, 22, 44, 68, 70, 72, and 73, along with their respective dependent claims, separately define over the prior art based on all the features recited in each of the claims as follows.

Claim 11 distinguishes over the prior art which fails to teach or suggest:

An implantable prosthesis for a tissue or muscle defect, the implantable prosthesis comprising:

a first layer of material that permits the formation of adhesions with tissue or muscle;

a second layer of material that permits the formation of adhesions with tissue or muscle, the second layer being attached to the first layer;

at least one pocket formed between the first and second layers;

a layer of barrier material that is resistant to the formation of adhesions with tissue or muscle, the layer of barrier material being attached to at least the second layer only at discrete locations;

a peripheral edge;

an outer area disposed inwardly of the peripheral edge;

an inner area disposed inwardly of the outer area; and

a first reinforcing member substantially surrounding the outer area and being constructed and arranged to reinforce at least the outer area.

Claim 15 distinguishes over the prior art which fails to teach or suggest:

An implantable prosthesis for a tissue or muscle defect, the implantable prosthesis comprising:

a first layer of material that permits the formation of adhesions with tissue or muscle;

a second layer of material that permits the formation of adhesions with tissue or muscle, the second layer being attached to the first layer;

at least one pocket formed between the first and second layers; and

a layer of barrier material that is resistant to the formation of adhesions with tissue or muscle, the layer of barrier material being attached to at least the second layer only at discrete locations;

wherein the layer of barrier material covers an entire surface of the second layer.

Claim 16 distinguishes over the prior art which fails to teach or suggest:

An implantable prosthesis for a tissue or muscle defect, the implantable prosthesis comprising:

a first layer of material that permits the formation of adhesions with tissue or muscle;

a second layer of material that permits the formation of adhesions with tissue or muscle, the second layer being attached to the first layer;

at least one pocket formed between the first and second layers; and

a layer of barrier material that is resistant to the formation of adhesions with tissue or muscle, the layer of barrier material being attached to at least the second layer only at discrete locations;

wherein the layer of barrier material comprises ePTFE.

Claim 21 distinguishes over the prior art which fails to teach or suggest:

An implantable prosthesis for a tissue or muscle defect, the implantable prosthesis comprising:

a first layer of material that permits the formation of adhesions with tissue or muscle;

a second layer of material that permits the formation of adhesions with tissue or muscle, the second layer being attached to the first layer;

at least one pocket formed between the first and second layers;

a layer of barrier material that is resistant to the formation of adhesions with tissue or muscle, the layer of barrier

material being attached to at least the second layer only at discrete locations;

a peripheral edge;

an outer area disposed inwardly of the peripheral edge; and

an inner area disposed inwardly of the outer area, wherein the at least one pocket formed between the first and second layers comprises at least one first pocket formed in the inner area and at least one second pocket formed in the outer area and separate from the at least one first pocket, the at least one second pocket including an access opening for gaining access to an interior of the at least one second pocket.

Claim 22 distinguishes over the prior art which fails to teach or suggest:

An implantable prosthesis for a tissue or muscle defect, the implantable prosthesis comprising:

at least one layer of material, at least a portion of which permits the formation of adhesions with tissue or muscle, the at least one layer including a peripheral edge, an outer area disposed inwardly of the peripheral edge, and an inner area disposed inwardly of the outer area;

a pocket formed in the at least one layer;

a first reinforcing member coupled to the at least one layer and surrounding the outer area, the first reinforcing member being constructed and arranged to reinforce at least the outer area; and

a second reinforcing member inwardly spaced from the first reinforcing member, the second reinforcing member being coupled to the at least one layer.

Claim 44 distinguishes over the prior art which fails to teach or suggest:

An implantable prosthesis for a tissue or muscle defect, the implantable prosthesis comprising:

at least one layer of material, at least a portion of which permits the formation of adhesions with tissue or muscle, the at least one layer including a peripheral edge, an outer area disposed inwardly of the peripheral edge and an inner area disposed inwardly of the outer area;

at least one first pocket formed in the inner area; and

at least one second pocket formed in the outer area and separate from the at least one first pocket, the at least one second pocket including at least one access opening for gaining access to an interior of the at least one second pocket.

Claim 68 distinguishes over the prior art which fails to teach or suggest:

An implantable prosthesis for a tissue or muscle defect, the implantable prosthesis comprising:

at least one layer of material, at least a portion of which is susceptible to the formation of adhesions with tissue or muscle, the at least one layer of material comprising a first layer of mesh material and a second layer of mesh material attached to the first layer of mesh material, the at least one layer including a peripheral edge, an outer area disposed inwardly of the peripheral edge and an inner area disposed inwardly of the outer area;

at least one first pocket formed in the inner area and defined by attachment of the first and second layers of mesh material; and

at least one second pocket formed in the outer area and defined by attachment of the first and second layers of mesh material, the at least one second pocket being separate from the at least one first pocket, each of the at least one first and second pockets including an access opening for gaining access to an interior of the respective at least one pocket;

a first reinforcing member coupled to the at least one layer and substantially surrounding the outer area, the first reinforcing member being constructed and arranged to reinforce at least the outer area; and

a second reinforcing member inwardly spaced from the first reinforcing member, the second reinforcing member being coupled to the at least one layer.

Claim 70 distinguishes over the prior art which fails to teach or suggest:

An implantable prosthesis for a tissue or muscle defect, the implantable prosthesis comprising:

at least one layer of material, at least a portion of which is susceptible to the formation of adhesions with tissue or muscle, the at least one layer of material comprising a first layer of mesh material and a second layer of mesh material attached to the first layer of mesh material, the at least one layer including a peripheral edge, an outer area disposed inwardly of the peripheral edge and an inner area disposed inwardly of the outer area;

a barrier layer that substantially inhibits the formation of adhesions with tissue, the barrier layer being attached to at least the second layer of mesh material;

at least one first pocket formed in the inner area and defined by attachment of the first and second layers of mesh material; and

at least one second pocket formed in the outer area and defined by attachment of the first and second layers of mesh material, the at least one second pocket being separate from the at least one first pocket, each of the at least one first and second pockets including an access opening for gaining access to an interior of the respective at least one pocket;

a first reinforcing member coupled to the at least one layer and substantially surrounding the outer area, the first reinforcing member being constructed and arranged to reinforce at least the outer area; and

a second reinforcing member inwardly spaced from the first reinforcing member, the second reinforcing member being coupled to the at least one layer.

Claim 72 distinguishes over the prior art which fails to teach or suggest:

An implantable prosthesis for a tissue or muscle defect, the implantable prosthesis comprising:

at least one layer of material, at least a portion of which is susceptible to the formation of adhesions with tissue or muscle, the at least one layer of material comprising a first layer of mesh material and a second layer of mesh material attached to the first layer of mesh material, the at least one layer including a peripheral edge, an outer area disposed inwardly of the peripheral edge and an inner area disposed inwardly of the outer area;

a barrier layer that substantially inhibits the formation of adhesions with tissue, the barrier layer being attached to at least the second layer of mesh material;

at least one pocket defined by attachment of the first and second layers of mesh material, the at least one pocket including an access opening for gaining access to an interior of the at least one pocket; and

a reinforcing member coupled to the at least one layer and substantially surrounding the outer area, the first reinforcing member being constructed and arranged to reinforce at least the outer area.

Claim 73 distinguishes over the prior art which fails to teach or suggest:

An implantable prosthesis for repairing a tissue defect, the implantable prosthesis comprising:

an ingrowth layer, at least a portion of which is susceptible to the formation of adhesions with tissue or muscle, the ingrowth layer comprising a first layer of mesh material, a second

layer of mesh material attached to the first layer of mesh material, and at least one first pocket disposed therebetween, the ingrowth layer including an inner central area and an outer peripheral area surrounding the inner central area; the prosthesis further comprising at least one of:

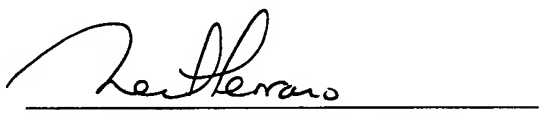
a) a barrier layer that substantially inhibits the formation of adhesions with tissue, the barrier layer being attached to at least the second layer of mesh material;

b) first and second reinforcing members coupled to the ingrowth layer, the first reinforcing member surrounding the outer peripheral area and being constructed and arranged to reinforce at least the entire outer peripheral area, the second reinforcing member being inwardly spaced from the first reinforcing member; and

c) at least one second pocket formed in the outer peripheral area and separate from the at least one first pocket, each of the at least one first and second pockets including an access opening for gaining access to an interior of the respective at least one pocket.

If there are any questions concerning the foregoing, the Examiner is requested to contact the undersigned at the number listed below.

Respectfully submitted,

By: 

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Date: May 26, 2004
Docket No. D0188.70132US00
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Christine A. Gardner

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Commissioner for Patents
P.O. Box 1450
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TRANSMITTAL

Sir:

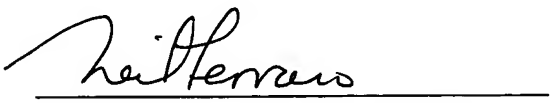
Transmitted herewith is/are the following document(s):

- [X] Fee Transmittal Form;
- [X] Check in the amount of $1,660.00 for issue fee, publication fee, and ten (10) copies of issued patent;
- [X] Comment on Statement of Reasons for Allowance;
- [X] Certificate of Mailing; and
- [X] Return Receipt Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

A check in the amount of $1,660.00 is enclosed. If any further amount is due, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By: 

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